Remarks

Claims 1 to 3 and 6 to 15 were pending. By this Amendment, claims 1, 14, and 15 were amended. No new matter has been added thereby and accordingly entry of the amendments is respectfully requested. Claims 1 to 3 and 6 to 15, as amended, are now pending and before the Examiner.

The Examiner objected to claims 1, 14, and 15.

In response, applicants have amended claims 1, 14, and 15 and maintain that such amendments render the Examiner's objection moot. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the objection.

The Examiner rejected claims 1 to 3 and 6 to 15 as allegedly obvious under 35 U.S.C. § 103(a) over Friedl *et al.* (U.S. Patent Publication No. 2005/0089575) in light of Gendron *et al.* (U.S. Patent Publication No. 2002/0137678), Parikh (Handbook of Pharmaceutical Granulation Technology), and the EPA Profile of the Pharmaceutical Manufacturing Industry ("EPA Profile").

Applicants respectfully traverse the rejection. Friedl *et al.* does not teach or suggest the use of "poloxamers having an average molecular weight of about 2000 to 12000", as the pending claims require. The claimed invention is based on the finding that the speed and extend of dissolution of the active agent telmisartan is unexpectedly improved by combining a basic agent and a poloxamer. Thus, in a test dissolution assay (pH 4.0) more than 75% of 40 mg telmisartan was dissolved after 30 minutes if in the presence of 40 mg meglumine and 4% poloxamer Pluronic 68, while less than 50% was dissolved in the same time period in the same formulation lacking the poloxamer. After 60 minutes, in the presence of poloxamer about 80% of telmisartan had been dissolved, whereas in the same time period, in the absence of poloxamer, only 55% had dissolved. Friedl *et al.* does not teach, suggest, or hint at such an unexpected and valuable advantage of the claimed invention.

It should also be noted that Friedl *et al.* considered surfactants and emulsifiers as optional and not essential excipients, because the manufacturing process of Friedl *et al.* relies on spray-drying. The compositions described in Friedl *et al.* are unsuitable for the simpler fluid bed

granulation process. Thus, the preferred amount of surfactant (0.05-1%) mentioned in Friedl *et al.* at paragraph [0058] is quite different from the preferred amount according to the present invention. Friedl *et al.* accordingly provides no motivation for one of skill in the art to use the amount of surfactants and emulsifiers similar to those of the claimed invention. Furthermore, the hygroscopicity of the tablets made according to the instant claims are very low up to 80% RH. In contrast, the hygroscopicity of the tablets made according to Friedl *et al.*, even in low RH conditions, which is an advantage for handling the tablets and provides a significant product and marketing advantage. Furthermore, the coating of carrier particles in a fluidized bed as mentioned in Friedl *et al.* is not the same as fluid-bed granulation referred to as the preferred formulation technique in the claimed invention as this technique does not involve the coating of particles with telmisartan.

Nor does Gendron *et al.*, Parikh, or the EPA Profile art provide what Friedl *et al.* lacks. For example, it is improbable that Gendron *et al.* would be consulted by a person skilled in the art at all, because Gendron *et al.* specifically relates to proteinaceous substances as active agents, which would not include telmisartan. Moreover, paragraph [0072] does not teach that Pluronics or other specified compounds have been known to improve the solubility of poorly water-soluble compounds in general but just that these Pluronics or other specified compounds can be used as co-solvents for tbdn-1 agents of limited solubility and are commercially available. There is no indication or hint that this teaching concerning tbdn-1 agents of limited solubility is somehow applicable to compounds such as telmisartan. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection.

Applicants submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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